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A RESEARCH ON: PERFORMANCE AND EFFICACY OF NATURAL SUPER DISINTEGRANT PSYLLIUM HUSK COMPARED TO CROSPOVIDONE AND SODIUM STARCH GLYCOLATE.

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ABSTRACT: In this study, sodium starch glycolate and crospovidone, two artificial super disintegrants, are compared to the natural super disintegrant psyllium husk in orodispersible tablets (ODTs). A natural, affordable, and biodegradable alternative called psyllium husk was compared to popular synthetic super disintegrants that are renowned for their quick disintegration speeds. The mechanical strength, disintegration time, and dissolving rate of the formulations were evaluated. The results indicated that psyllium husk had equivalent performance with the added advantages of being natural and non-toxic, whereas synthetic super disintegrants produced quicker disintegration and greater dissolving rates. The results show that psyllium husk can be a sustainable and workable substitute for synthetic super disintegrants in ODT formulations; nevertheless, more tuning is required to maximize its potential.

Keywords: Natural superdisintegrate, Or dispersible Tablets, Drug Release Study, Psyllium Husk, Crospovidone.

INTRODUCTION

The capacity of or dispersible tablets (ODTs) to dissolve quickly in the mouth without the need for water has drawn a lot of attention lately. This ability to do so improves patient compliance, particularly for elderly, bedridden, and paediatric patients. The oral route is still the most convenient, economical, and straightforward way to administer medication. Nevertheless the problem of dysphagia difficulty swallowing among some patient populations calls for the creation of substitute dose forms, such as ODTs. ((Dey and Maiti, 2010)

For ODTs to break down quickly when they come into contact with saliva, super disintegrants are an essential component of the formulation. Because they work so well at

accelerating disintegration and improving medication dissolving, synthetic super disintegrants such sodium starch glycolate and crospovidone are often utilized. Yet, psyllium husk is being investigated as a possible natural super disintegrate as a result of the hunt for safe, non-toxic, and biodegradable substitutes. (Ghourichay *et al.*, 2021)

Plantago ovate seeds are the source of psyllium husk, which is well-known for having a high fibres content and the ability to absorb water. Its natural polymer composition provides benefits including cost-effectiveness, safety, and biocompatibility. The purpose of this study is to evaluate the effectiveness and performance of sodium starch glycolate and crospovidone, two artificial super disintegrates, in ODT formulations compared to psyllium husk.(Madgulkar, Rao and Warrier, 2014), (Przybyszewska *et al.*, 2024)

This study looks at psyllium husk's potential as a sustainable substitute for synthetic super disintegrate in the formulation of ODTs by assessing factors including mechanical strength, disintegration time, and dissolving rate. The results of this comparative investigation may lead to the development of pharmaceutical formulations that are more patient- and environmentally-friendly, which would further improve drug delivery methods. (Mehta *et al.*, 2011)

Ideal properties of ODTs: (Hirani *et al.*, 2009), (Dey and Maiti, 2010b), (Hannan *et al.*, 2016)

The technology employed in the production of ODTs affects their performance. Such pills must have the capacity to dissolve quickly and spread or dissolve in saliva in order to eliminate the need for water. Numerous technologies have been created to allow ODT to carry out this special duty. An optimal ODT should fulfil the subsequent requirements:

- Disintegrates and dissolves in the oral cavity in a matter of seconds without the need for water during oral administration.
- Possesses enough strength to endure the rigors of manufacture as well as handling after manufacturing.
- Permit a lot of medication loading.
- Feels good in the mouth.
- is not affected by external factors like temperature and humidity
- It’s flexible and compatible with the processing and packaging equipment already in use.

Challenges in formulating ODTs: (Hirani *et al.*, 2009), (Malaak *et al.*, 2019)

1. **Palatability:** Since most medications are tasteless, oral disintegrating drug delivery systems often include the medication in a form that masks its flavour. Drug delivery systems breakdown or disintegrate in the patient's mouth, releasing the active chemicals that come into touch with their taste buds. For this reason, it is essential to mask the drug's flavour for the patient to comply with treatment.
2. **Mechanical strength:** Because ODTs are compressed into tablets with very low compression force, or because they are made of very porous and soft-moulded matrices, they are able to disintegrate in the oral cavity. This makes the tablets brittle and/or friable, difficult to handle, and frequently in need of specialized peel-off blister packing, which could raise the cost of the product.
3. **Hygroscopicity:** With typical temperature and humidity levels, a number of orally disintegrating dosage forms become hygroscopic and lose their physical integrity. Therefore, they require humidity protection, necessitating specific product packaging.
4. **Amount of drug:** The quantity of medication that may be added to each unit dosage restricts the deployment of ODT technology. The medication dosage for lyophilized dosage forms has to be less than 60 mg for soluble medications and less than 400 mg for insoluble pharmaceuticals. This characteristic presents a significant challenge when creating oral films or wafers that dissolve quickly.

5. **Aqueous solubility:** The creation of eutectic mixes, which induce freezing-point depression and the formation of a glassy solid that may collapse upon drying due to loss of supporting structure during the sublimation process, is one of the many formulation problems associated with water-soluble medications. Sometimes, this kind of collapse may be avoided by adding other matrix-forming excipients, such mannitol, which can cause crystallinity and provide the amorphous composite stiffness.

Isolation of polysaccharide from Plantago ovate husk:

To fully release the mucilage into the water, the Plant ago ovate husk was cooked for a short while after being soaked in distilled water for 48 hours. In order to filter and separate the marc, the material was pressed through muslin fabric. To precipitate the polysaccharide, an equivalent amount of acetone was then added to the filtrate. Before being used, the separated polysaccharide was powdered, sieved (#80), and kept in a desiccators after being dried in an oven at a temperature lower than 60°C.(Pawar and Varkhade, 2014), (Neto *et al.*, 2017)

Preformulation study: (Kinani and Taghi, 2022), (RaoS *et al.*, 2015), (Kinani and Taghi, 2022b), (Gaikwad, Rane and Jain, 2022)

1. Melting point: Melting point equipment was used to ascertain the drug's melting point. This was contrasted with a drug's stated melting point value.

2. **Determination of Analytical Wavelength (λ max):** A precise weighing of 10 mg of quercetin was dissolved in water in a 100 ml volumetric flask to create a standard stock solution of 100 µg/ml. The volume was then increased to 100 ml with water. Ten millilitres (ml) were pipette into a 100 millilitre volumetric flask from the stock solution. With water, the capacity was increased to 100 ml. Between 200 and 400 nm, the resultant solution, which contained 10µg/ml, was scanned.

3. **Bulk density:** It is the proportion of the powder's bulk volume to its overall mass. The weighed powder was poured into a measuring cylinder, and the starting weight was recorded. The bulk volume was the name given to this first volume. Based on this, the bulk density was computed using the following formula. It is provided by and stated in gm/ml.

Bulk density (D_b) = Mass (M) / Bulk volume (V_b)

Where

M is the mass of powder,

V_b is the bulk volume of the powder

4. Tapped density: It is the proportion of the powder's total mass to its tapped volume. The powder was tapped 750 times to determine the volume, and if there was a difference of less than 2% between the two volumes, the tapped volume was recorded. If it is greater than 2%, 1250 toppings are made, and the volume of each tap is recorded. In a bulk density apparatus, tapping was done until the difference between successive volumes was less than 2%. It is provided by and stated in gm/ml.

Tapped density (Dt) = Mass (M) / Tapped volume (V_t)

Where, M is the mass of powder; V_t is the tapped volume of the powder.

5. **Angle of repose:** The funnel method was utilized to ascertain the powder's angle of repose. The powder was taken via a funnel after being precisely weighed. The funnel's height was modified such that the tip of the funnel just touched the top of the powder pile. The powder was let to freely pour onto the surface through the funnel. The following formula was used to determine the angle of repose and estimate the diameter of the powder cone.

$\theta = \tan^{-1} h / r$

Where, h and r are the height and radius of the powder cone, respectively.

6. Carr's index: Particle size, cohesiveness, and relative flow rate all have an indirect bearing on it. It is an easy, well-liked, and quick way to forecast the properties of powder flow. The following formula was used to calculate the bulk drug's % compressibility. It is based on the apparent bulk density and the tapped density.

$$\% \text{ compressibility index} = \frac{tapped\ density - initial\ bulk\ density}{tapped\ density} \times 100$$

7. **Hausner's ratio:** The Hausner's ratio is the ratio of the tapped density to the bulk density. It serves as a figurative indicator of powder flow easiness. The formula that follows is used to compute it.

Hausner's ratio = Tapped density (D_t) / Bulk density (D_b)

Direct Compression method: Using this process, the medication and excipient combination is compressed straight into tablets without any prior preparation. It is necessary for the mixture to be crushed to have acceptable flow characteristics. Few medications can be directly crushed into reasonably-quality pills. The concentration and use of disintegrates are more crucial. Particle size, hardness, pore size, and water absorption capacity are other aspects taken into account. Therefore, the disintegrate addition technique is simple to use and reasonably priced. (Podczeck, 2008)

POST COMPRESSION EVALUATION: (Pawar *et al.*, 2014), (Puttewar *et al.*, 2010), (Segale *et al.*, 2007), (Elkhodairy, Hassan and Afifi, 2014)

1. **Weight variation:** A computerized weighing balance was used to calculate the weights of each of the twenty tablets, both individually and collectively. From the total weight, the average weight of a single pill was calculated. The individual tablet's percentage deviation was computed by comparing the average weight to the individual weight.
2. **Thickness:** The vernier calliper of the Electro Lab type was used to measure the tablets' thickness. Every batch has five pills chosen at random. It is reported in millimetres (mm), and average values were computed.
3. **Hardness:** Using a Monsanto hardness tester, the hardness of each formulation was ascertained by removing five tablets. The kg/cm3 unit of measurement was used to express the hardness.
4. **Friability:** A Roche friabillator (Omega India) was used to gauge the tablet's friability. Twenty reweighed tablets were turned 100 times at a speed of 25 revolutions per minute for four revolutions, dropping the tablets six inches each time. After deducting the pills with a soft muslin cloth, they were weighed again, and the percentage of weight reduction was computed. The following formula was used to calculate the tablets' % friability.

   Percentage friability = (Initial weight – final weight/ Initial weight) ×100
5. **Disintegration time:** Disintegration test equipment was used to measure the disintegration time. Each of the basket's six tubes held a tablet. The basket's bottom surface is composed of a stainless steel screen (mesh number 10) that was submerged in water kept at 37°C to act as a disintegration fluid. A 100 rpm paddle was utilized as a stirring element. The duration in seconds required for the tablet to completely dissolve and leave no edible substance inside the device was recorded.
6. **Drug content:** After being weighed, ten tablets were pulverized from each batch. A pH 6.8 phosphate buffer containing 100 millilitres of the necessary powder, or 4 milligrams of quercetin, was added. Using whatmann filter paper, 1 millilitre of this solution was obtained, and it was subsequently increased to 100 millilitres by adding phosphate buffer (pH 6.8). UV visible spectrophotometer was used to analyze the fluid for drug content at 372 nm.
7. **In-vitro dissolution study:** Using 900 cc of pH 6.8 phosphate buffer at 37±0.5º C as the dissolving media and a paddle stirrer running at 50 rpm, the in vitro dissolution of the or dispersible tablets was investigated in a USP type-II dissolution test device. Every test utilized a single pill. At certain intervals, aliquots of the dissolving mixture were taken out and the absorbance at 372 nm was measured to determine the drug concentration. A new volume of dissolving liquid was added to the volume removed at each time interval. Plotting the cumulative proportion of the medication released against time was done.

RESULT:

1. **Melting point:** The melting point of quercetin was determined by the capillary method and was found to be 307ºC which is in the range specified in the official limits.
2. **Determination of Analytical Wavelength (λ max):** With phosphate buffer (pH 6.8) serving as the blank, a strong peak was seen at 372 nm, indicating that the analytical wavelength is 372 nm. The quercetin medication solution was scanned between 200 and 400 nm using a UV spectrophotometer. The result falls between the ranges given in the official monograph and it is shown in Fig No.1

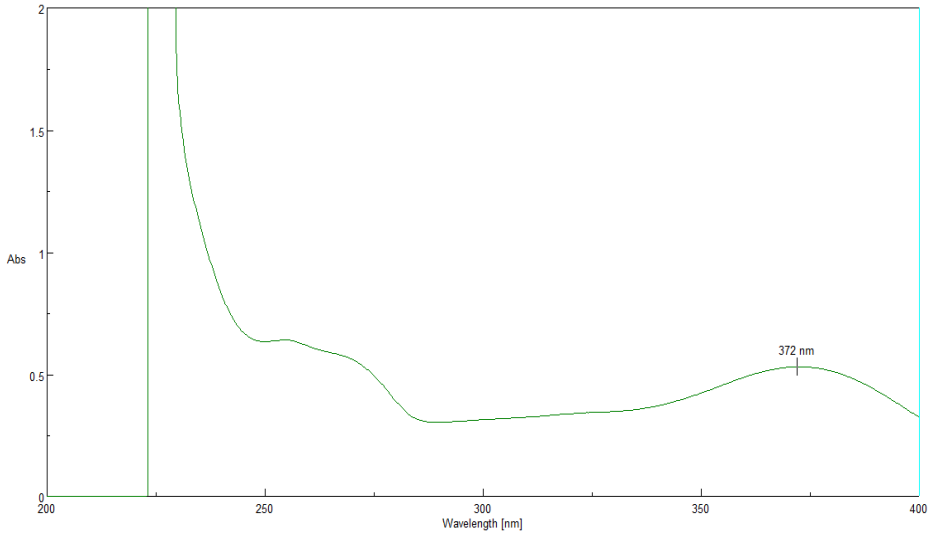

Figure no. 01: (λ_{max}) of quercetin

3. **Fourier Transform Infrared Spectroscopy (FTIR) Study:** Using an IR spectrophotometer, the FTIR spectra of the drugs quercetin and crospovidone, drug and sodium starch glycolate, and drug and psyllium husk were recorded. The prepared samples were scanned at 4000-400 cm-1. The FTIR spectrum is displayed in Figure No. below. The main purposes of the procedure are to identify each ingredient's functional group and look for any potential chemical interactions between them. Since FTIR is an extremely sensitive analytical technique, all component and formulation spectra were examined.

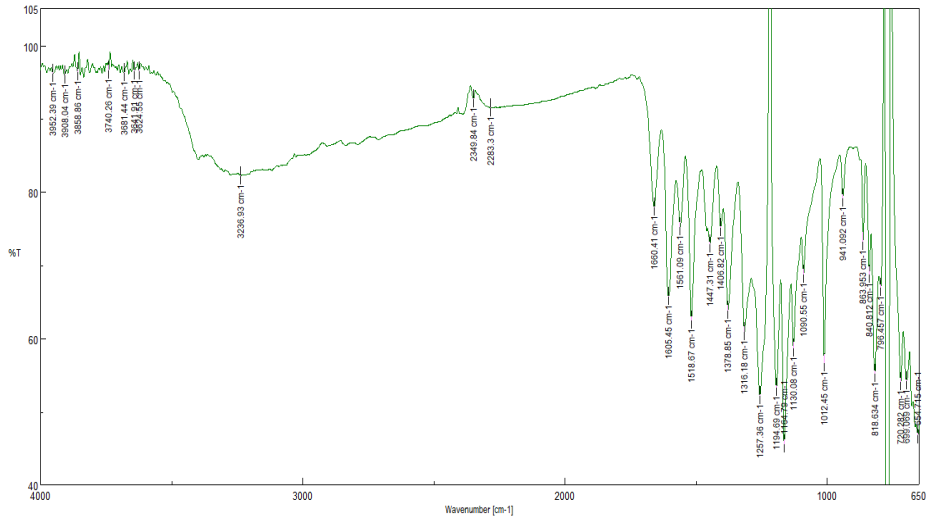

Figure No.02: FTIR Spectra of Quercetin

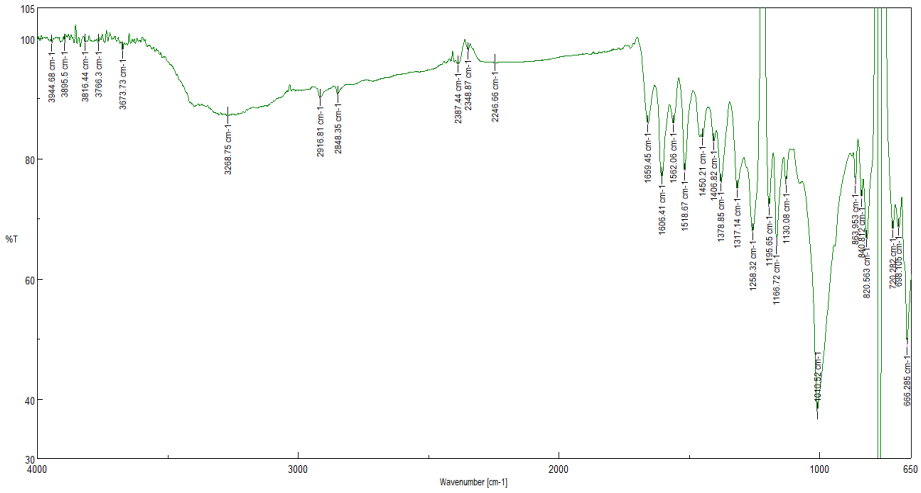

Figure No.03: Quercetin + crospovidone

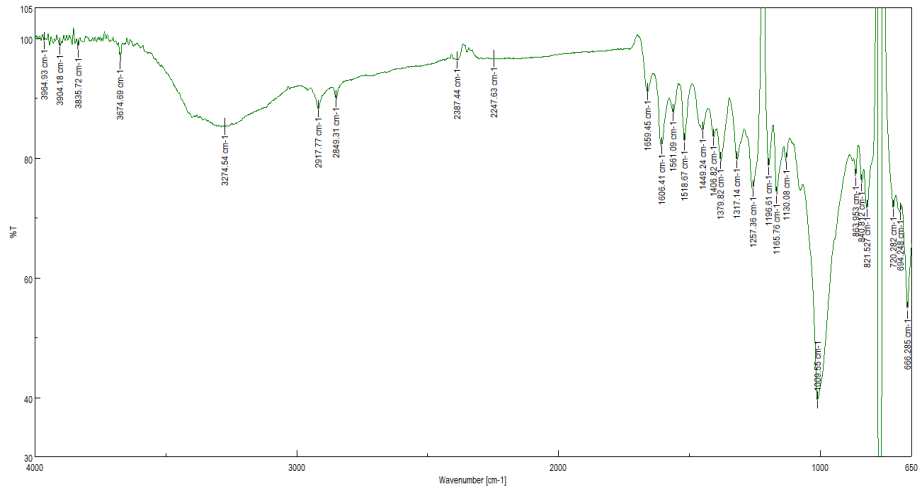

Figure No.04: Quercetin + sodium starch glycolate

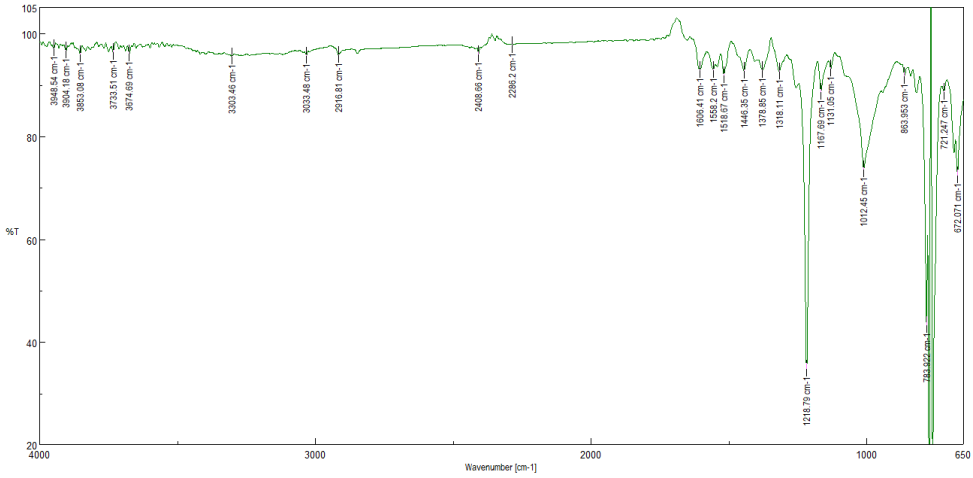

Figure No.05: Quercetin + Psyllium Husk

Table No. 02: Preformulation study

Formulation code	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Hausner's ratio	Compressibility index	Angle of repose
F1	0.313±0.005	0.369±0.008	1.17±0.011	15.7±0.08	28.70±1.21

F2	0.317±0.005	0.360±0.004	1.13±0.009	11.94±0.78	28.39±1.12
F3	0.310±0.003	0.359±0.003	1.15±0.007	13.64±0.07	29.60±1.09
F4	0.309±0.004	0.356±0.001	1.15±0.008	13.20±0.15	28.95±1.11
F5	0.309±0.012	0.360±0.005	1.16±0.004	14.16±0.05	28.07±1.56
F6	0.302±0.007	0.350±0.003	1.15±0.005	13.71±0.03	27.95±0.48
F7	0.305±0.020	0.358±0.002	1.17±0.015	14.80±0.09	29.35±0.05
F8	0.313±0.015	0.360±0.001	1.15±0.017	13.05±0.23	29.29±1.17
F9	0.302±0.001	0.340±0.002	1.12±0.002	11.20±0.16	27.89±1.07

Table: Data (mean ± standard deviation) of Preformation studies for each formulation

Table No.03: Post formulation Study

Formulation code	Weight variation (mg)	Thickness (mm)	Friability (%)	Hardness (kg/cm^2)	Disintegration time (sec)	Drug content (%)
F1	151.20±0.7	2.65±0.03	0.22±0.2	3.5±0.2	100±0.7	96.41±1.5
F2	149.95±1.1	2.60±0.6	0.24±0.3	3.5±0.18	95±0.5	97.33±1.2
F3	152.32±0.4	2.70±0.1	0.21±0.2	3.5±0.2	90±1.3	98.12±1.3
F4	152.45±0.9	2.73±1.7	0.19±0.1	4.0±1.2	75±0.1	97.14±1.2
F5	151.36±0.6	2.65±0.4	0.21±0.8	3.5±0.18	80±0.12	98.29±1.5
F6	150.78±0.9	2.63±0.17	0.20±0.1	3.5±0.2	82±0.2	98.58±1.5
F7	151.95±2.0	2.67±0.9	0.21±0.2	4.0±0.3	62±1.6	98.71±1.4
F8	149.59±1.3	2.60±0.02	0.24±1.2	3.0±0.12	54±1.2	98.86±1.5
F9	151.29±1.3	2.64±0.7	0.21±0.3	3.5±0.8	46±0.5	99.29±1.1

In-vitro drug release study:

Table No. 04: In-Vitro Drug Release Study of All Formulated Batches

Time (min)	**% CDR**								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
0	0	0	0	0	0	0	0	0	0
5	54.38	59	51.46	70.42	70.12	71.6	70.16	70.11	70.11

10	57.38	65.72	61.74	74.40	73.62	75.35	74.17	77.11	79.10
15	70.74	72.07	69.05	77.59	78.09	79.69	82.34	82.98	89.58
20	84.80	87.65	85.35	83.40	83.25	85.60	87.17	88.55	95.34
25	88.48	89.12	88.82	89.09	88.44	88.67	93.66	94.35	99.93
30	92.35	93.57	92.73	91.62	92.12	93.99	97.54	98.12	-

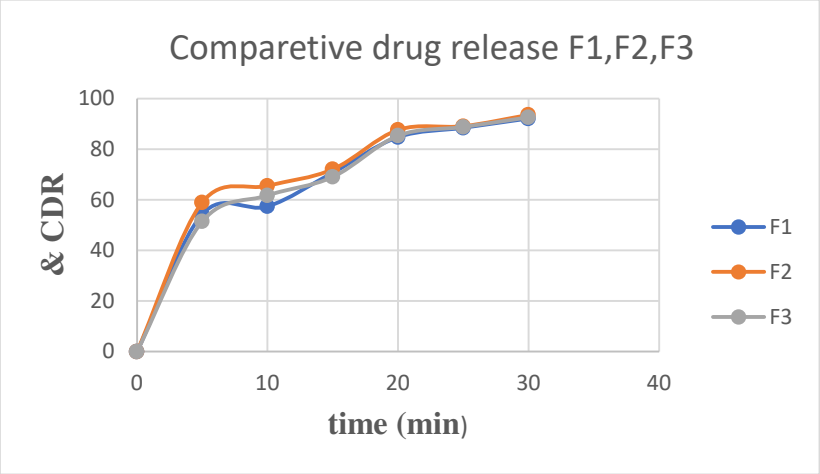

Figure No.16 Comparative Drug Release of F1, F2, F3

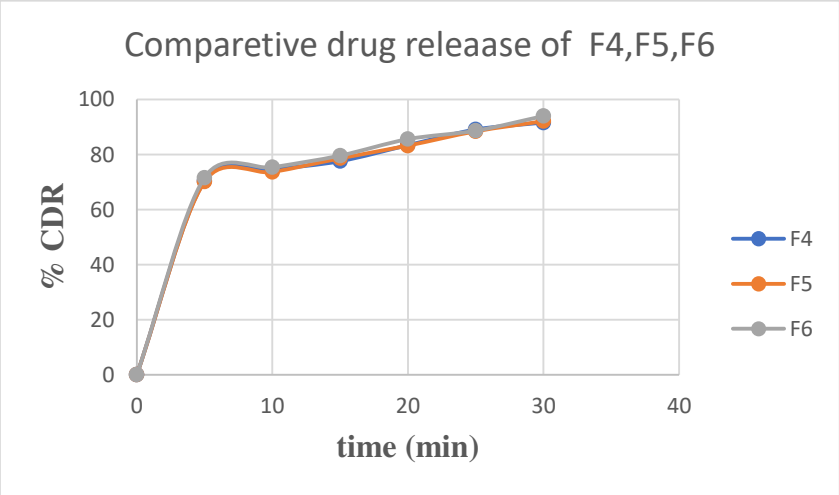

Figure No.17 Comparative Drug Release of F4, F5, F6

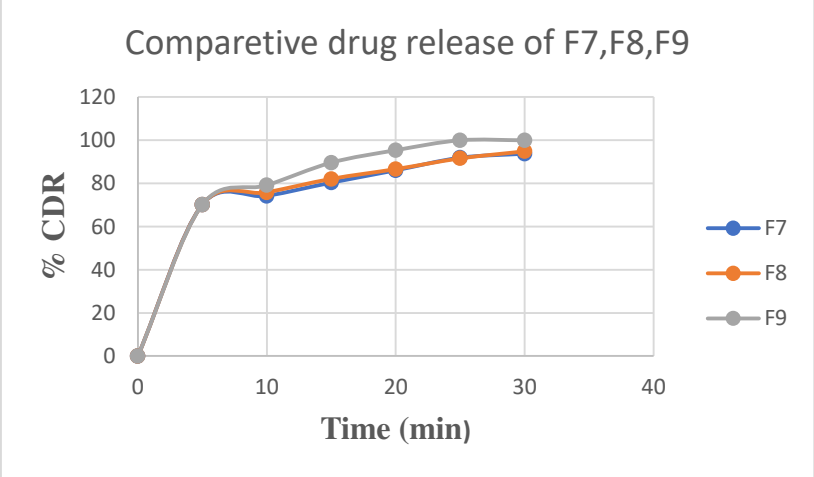

Figure No.18 Comparative Drug Release of F7, F8, F9

CONCLUSION: This study conducted a thorough comparison of the performance of sodium starch glycolate and crospovidone, two synthetic super disintegrants, and natural psyllium husk in the formulation of orodispersible tablets (ODTs). The findings showed that whereas synthetic disintegrants showed higher rates of dissolution and faster disintegration times, psyllium husk showed similar effectiveness along with the benefits of being natural, biodegradable, and reasonably priced. The exceptional disintegrant properties of psyllium husk highlight its potential as a sustainable substitute in medication formulations. Its efficacy may be increased by more study and optimization, opening the door to patient- and environmentally-friendly medication delivery methods. This work highlights the practicality of natural polymers in contemporary pharmaceutical applications, contributing to the continuous progress in drug delivery technology.

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